THE LOS ANGELES CUSTOMS BROKERS & FREIGHT FORWARDERS ASSOCIATION, INC.

1949 - 2003 Serving Our Industry for 54 Years

April 3, 2003

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852
Office of Information and Regulatory Affairs

FDA Proposed Food Regulations
Dockets Number 02N-0276 and 02N-0278

Dear Sirs:

The Los Angeles Customs Brokers & Freight Forwarders Association ("LACBFFA") brings together more than 250 licensed Customs Brokers and freight forwarders doing business in the Southern California. Since 1949, our Association has served as the voice for federally licensed international trade professionals seeking to encourage, aid and maintain a high standard of efficiency among customs brokers and freight forwarders, with a view toward protecting the interests of the government, importers, customs brokers and freight forwarders while insuring fair, equitable and uniform administration of Federal laws governing our nation's imports and exports. Our Association recognizes and supports the efforts of the FDA and other federal agencies to secure our border under the heightened sensitivities and needs in this new age of anti-terrorist concerns.

Our members are responsible for the transmission of entry documentation for many importers throughout the country and will now be subject to the proposed food regulations published by the Food & Drug Administration in the *Federal Register* on February 3, 2003. The Association has collected comments to the proposed FDA food regulations from its membership and the following document sets forth the many of concerns, thoughts and suggestions brought to the Association's direct attention.

02N-0278 C 101

Post Office Box 4250, Sunland, California 91041 • Telephone: (818) 951-2841 • FAX: (818) 353-5976 • E-Mail: la.cbffa@verizon.net
Website: www.lacbffa.org

THE LOS ANGELES CUSTOMS BROKERS & FREIGHT FORWARDERS ASSOCIATION, INC.

1949 - 2003 Serving Our Industry for 54 Years

In summary, the members of the LACBFFA are apprehensive that our members and the importers they serve will be unable to operate if the proposed regulations are finalized in their present form and are equally concerned with the possibility that unsafe food product may enter U.S. commerce. Members of the Association as a single voice have indicated their commitment to comply with the FDA's food requirements but are concerned by what appears to be the FDA's lack of information from affected food businesses, importers and brokers. Especially in the arena of perishable foods, the proposed regulations seem to promise only that U.S. importers may soon be out of business --- as food articles remain portside and unmarketable as a result of the inability to comply with technical, impractical regulations, and for no reason related to food safety or product integrity.

The Association believes in the mandate of the underlying Congressional legislation – the Bioterrorism Preparedness Act of 2002 --- leading to the proposed FDA implementing regulations, but also believes that the FDA has not availed itself of sufficient trade input in the drafting of these regulations. The proposed regulations threaten the entire international food industry for no apparent or obvious reason. There is no evidence that the FDA has made an effort to utilize existing systems, to rely upon available pre-arrival information or to anticipate real-world consequences of their proposed regulations. We strongly encourage the FDA to take advantage of this brief comment period, and the ensuing months before publication of final regulations, to enter into an extensive dialogue with the trade community to build upon existing business practices and government systems to most efficiently address the concerns under the Act.

The following comments first express the collective concerns of the Association's members and, then, make some suggestions to the Agency for better implementation of its statutory obligations.

I. Concerns Regarding Proposed Regulations

A. Increased Liability

Of perhaps the greatest impact upon the Association's members is the increased liability to its members who will be the likely submitters of the Prior Notice documentation.

Post Office Box 4250, Sunland, California 91041 • Telephone: (818) 951-2841 • FAX: (818) 353-5976 • E-Mail: la.cbffa@verizon.net
Website: www.lacbffa.org

THE LOS ANGELES CUSTOMS BROKERS &
FREIGHT FORWARDERS ASSOCIATION, INC.
1949 - 2003 Serving Our Industry for 54 Years

The proposed regulations specifically state that the submitter of the Prior Notice is responsible for the accuracy of the information contained therein. But the Customs Broker, who is merely engaged by a U.S. importer to ensure timely submission of all documentation required for entry of a particular article, is not a party to any relevant transaction and has no basis upon which to question any information it receives from the importer, shipper or carrier. The Customs broker is not the importer of record and it is unacceptable to the Association's members and unrealistic of the FDA to shift liability for accuracy of submitted information from the importer of record to the Customs Broker by shifting burden to the "submitter" of the required documentation.

There is no amount of compensation that can adequately compensate the Customs Broker for its assumption of this level of liability. There is no insurance company that will insure the Customs Broker against claims brought against it by the FDA for failure to provide adequate or correct Prior Notice information. While there is no question that the Customs Broker must be permitted to file the Prior Notice document, there is also no doubt that it cannot be held liable by the FDA for any failure or insufficiency of that information.

The FDA has created no liability for the U.S. Agent in its role as a conduit of information between the Agency and the foreign food facility. Similarly, it should also specifically relieve the Customs broker from any liability to the FDA for its transmission of incomplete or inaccurate information contained within the Prior Notice documentation. Again, as between the foreign food facility and the U.S. Agent, any liability as to failure to perform must rest solely between the entity responsible for facilitating the transaction not the party merely communicating information given to it by those facilitators. The Customs Broker must be no more liable to the FDA as a submitter of the Prior Notice then the U.S. Agent is for its transmission of information between the FDA and the foreign food facility.

B. Registration Requirements

To protect the American supply of food articles, it is reasonable to require that the foreign exporter be registered with the FDA. The proposed rule indicates that all foreign and domestic food facilities must register, unless specifically exempted. In the case of perishable produce, for example, this may include, packinghouses, trucking companies, inspection stations and cold storage facilities (although the regulations are not clear on exactly which if any of these entitles

Post Office Box 4250, Sunland, California 91041 • Telephone: (818) 951-2841 • FAX: (818) 353-5976 • E-Mail: la.cbffa@verizon.net
Website: www.lacbffa.org

may be exempted from registration). However, no objective related to protecting the American food supply is served by requiring anyone other than the foreign exporter to register with the FDA since the exporter, or foreign shipper, is the entity holding the documentation tracking supply chain information and is, in fact, the party transacting the business governing the conditions of import.

Both U.S. Customs and the USDA require the exporter to be listed on the commercial invoice and the Phytosanitary Certificate. At no time is the U.S. Customs broker provided with information related to the packing house or repackager. Moreover, any grower information the Broker may receive will necessarily not contain the detail that the FDA proposed rule indicates will be required on the Prior Notice submission.

The exporter and the importer have contracted for the purchase and sale of the subject product. All payments and other consideration for the transaction are between those two parties. Accordingly, the only valid and "real" paper trail documenting the manufacture, transfer and receipt of the food item exists between those two parties. So long as the foreign exporter is registered with the FDA then the FDA will have access to any existing paper trail concerning the subject food article.

Shippers have a set of protocol of standards in place for the products they ship to the United States. Whether this protocol may include a bar code system or compliance with the HACCP (Hazard Analysis and Critical Control Points) Program, these procedures enable products to be tracked through the shipper to the packing house and original grower. Again, requiring registration of the shipper, or exporter, will enable the FDA to gain access to any and all paperwork detailing the processes relevant to any particular, imported food article.

C. Prior Notice Submissions

1. Prior Notice Information is Not Known At Time of Product Order

The FDA, in its analysis of various rulemaking proposals, indicates its belief that the information proposed to be included within the Prior Notice submission is available to importers at the time of ordering the product. This is simply not true --- especially in connection with the fresh produce and seafood industries. Seasonal contracts may be made between the importer and

the shipper and are fulfilled when the produce becomes available during the season --- an unknown date, an unknown time and an unknown quantity or particular type of product. Moreover, even things more reliable than the weather may influence when a particular shipment is exported – for example, the availability of a carrier or the lack of USDA pre-inspection may be relevant to actual shipment date or content. Simply stated, many different factors may influence when a particular item is shipped and not a single one of these may be known at the time of initial order placement.

The Association's membership urges the FDA to specifically seek input from the international food transport industry in order to better learn how realities of food shipment may differ from what was apparently assumed in drafting the proposed regulations. The fact is that oftentimes obtaining even the information presently required to be presented within 10 days after entry is difficult to learn. As one member most succinctly phrased it, "To demand this information no later than noon of the calendar day BEFORE arrival is not to understand the actualities of trade and transportation. Trade is not just the putting of cargo on a vessel...Practical thought needs to go into these proposals by the FDA or there will not be a marketplace to trample over."

2. Proposed Rulemaking Unnecessarily Requires Duplicative Work Effort

At the present time, FDA is receiving most of the information required on the Prior Notice through the OASIS system. Now, the FDA is also requesting that this information be provided to it through a new, untested Internet-based information system. The information to be transmitted through this new system is not merely a copy and paste from one information system to the other but, rather, will mandate the re-typing of identical information into two separate systems, inviting and promising typographical and clerical errors unrelated to any issue impacting upon food safety. Moreover, this repetitive work will require double the necessary personnel and staffing hours, driving the cost of doing business to an unacceptable level.

3. Submission of Supply Chain Information Should Be Sufficient

The submission of the registration number through its new system requires keying in registration information that could generate inadvertent clerical and typographical errors. FDA, however, has the information necessary to verify the registration information for any entity in the

supply chain identified by the importer or broker. Accordingly, FDA should take upon itself the onus of confirming validity of registration information through the development of its internal database systems and should not require importers or brokers to submit registration information that could unintentionally be incorrect leading to unnecessary arrival delays.

4. Grower Information Increases Workload Up to 100%

Through OASIS, brokers/importers are presently not required to immediately report grower information, but, rather, only the seller/shipper information related to a particular food product. When FDA elects to sample a shipment as a result of its review of the OASIS information, then the Agency is provided with relevant grower information.

Produce shipments often include products originating from one (1) to 200 shippers per shipment, with the average shipment including products from 50 different growers. If the importer/broker is automatically required to transmit grower information with its Prior Notice submissions for each separate line item contained within a single shipment, the present workload will increase more than 100%. Again, the increased man hours and personnel costs will drive the business to extinction for no obvious reason.

5. Inexplicable Expansion of Prior Notice Content

Without sufficient explanation, the FDA has required much more information to be submitted as a part of the Prior Notice than Congress intended pursuant to the Bioterrorism Preparedness Act of 2002. Interestingly, a lot of the information required by the FDA is currently provided to it as a part of the entry information it receives through OASIS, yet the Agency proposes that a separate, new Internet-based information system is necessary. In order to know much of the information required in the proposed Prior Notice submission, the Customs broker will have to actually process the Customs entry or "in-bond" documentation before actually submitting the pre-arrival information....5 days before anticipated arrival!

Congress intended the Prior Notice to serve as a base-line information about the product coming to shore so that the FDA could arrange for inspection of that product should it determine that such a sampling was necessary. The submission of the Prior Notice was not intended to be so time-consuming or work-intensive to warrant extraordinary, additional costs to import food

items or to require duplicative work effort. It violates that mandate to propose such complicated Prior Notice submissions, which guarantee exorbitant costs for importation and require repetitive submissions by the same importer or broker in connection with the identical food shipment to separate governmental agencies.

6. Unavailability of Necessary Documentation within Prescribed Time Period

Meeting the requirements for Prior Notice submission between 5 days prior to anticipated arrival and by noon of the calendar day before arrival provides too little flexibility to reflect the needs of real-world importers and brokers. Ocean arrivals may take from as little as 5 days or as many as 22 days to arrive. Rarely are documents available more than 3 days in advance of arrival and oftentimes they are not available until the day before delivery. Moreover, a particular chartered vessel may have over 40 entries with over 400 containers on a single ship and there may be 2 or more such vessels arriving during a particular day during peak season. Reviewing all of the subject documentation to retrieve just that and all of that required on the required Prior Notice submissions will be impossible to accomplish by noon of the calendar day before arrival.

7. Consistently Unavailable Arrival Information

It is oftentimes impossible to know exact arrival times of chartered vessels or aircraft to ensure the timely submission of the Prior Notice document and/or the timely update of that documentation. Even monitoring anticipated arrival times will not guarantee knowing the actual time the boat or plane arrives at port. Without staffing the ports 24 hours each day it will be impossible to guarantee that the Prior Notices can be timely updated with accurate arrival information – despite even the very best of efforts. Small brokers will necessarily be put out of business, as they will be unable to monitor the 24 hour operations of international carriers, providing the larger companies with unfair advantages over smaller competitors.

Moreover, many orders or purchases are shipped as a result of blanket orders incorporating seasonal consignments. These orders may consist of incremental shipments over a stated period of time, depending upon available transport and seasonal availability. Oftentimes, it is not possible to know exactly what portion of that blanket order has actually been shipped until it arrives at port. The proposal makes no provision for split shipments or unannounced division of shipments due to last minute unavailability of carrier space. Such differences

between information contained in the Prior Notice and that which may actually arrive are inconsequential in terms of verifying product integrity and, in fact, probably do not impact upon the FDA's decision on whether or not to sample or inspect a subject shipment or article upon arrival. Nevertheless such unforeseen alterations to food arrival times will cause the original Prior Notice to be inadequate and will require the additional, duplicative effort of submitting a second, substantially identical document to the FDA.

D. Arrival Determinations

1. Refusal Upon Arrival

The proposed regulations are unclear and ambiguous. When an entry is held at the port for inaccurate or untimely Prior Notice submission, are there time conditions for resubmission of this information? If the cause for refusal is merely a typographical error, may that mistake be corrected immediately or will there be a period of time during which perishable items will languish on the dock because a clerk inadvertently transposed two digits in a registration number? How will a release after re-submission of a Prior Notice impact a determination of admissibility? Will the shipment be subject to inspection upon submission of the Prior Notice and remain subject to a subsequent inspection once the FDA receives the entry documentation through OASIS? The proposed regulation indicates that any refusal will not be known until after OASIS filing, since it will only be at this point that the sufficiency (or insufficiency) of the Prior Notice, especially in the case of a food article which was not inspected upon arrival, may be determined. How then can the regulations propose that goods may not leave the port if the Prior Notice is deemed to be insufficient when, in fact, in most cases through OASIS occurs after the goods have at least been conditionally released.? These ambiguities do not ease the importing community's concerns regarding the appearance of finalized regulations.

2. Lack of Information/Availability re: Secured Storage Facilities

The proposed food regulations indicate that once an article is refused admission as a result of untimely or incomplete Prior Notice or failure of a required food facility to duly register, it must be held at an FDA-approved secured facility. Where are these facilities? Will there be a published list made available to the importing public prior to arrival so that a determination of ports of arrival may, in some part, be dependent upon available secured storage

facilities in the event the products are refused even conditional release? Members of the Association specifically bring to the FDA's attention that, during the produce season, the break-bulk produce is off loaded at a warehouse with no refrigeration. It is cleared and moved as soon as possible in order to retain marketability. It is important that, in considering its cold storage option, the FDA recall the Chilean grape incident in 1988 during which the cold storage facilities in South California filled to capacity in a little over two weeks time (and these were not bonded facilities).

3. Anticipated Port Congestion

With the incredible amount of information required on the Prior Notice submission, for all of the reasons set forth in these comments and otherwise, timely or accurate submissions in many cases simply will be impossible. Many of the impacted shipments will contain fresh or frozen perishable food items arriving on a 24 hour basis from Canada or Mexico. As the produce sits at the Port awaiting submission of a new, completely accurate Prior Notices (most of which information will then be duplicated on the post-entry submission required of Customs and again submitted to the FDA through OASIS), there inevitably will be inexcusable port congestion as insufficient refrigeration is relied upon by many different importers for loads and containers of perishable food products. This unnecessary congestion and port delay is especially troubling since as the new Prior Notices are being submitted to update anticipated arrival information, the food articles will be sitting at the Port available for inspection at any time.

E. Flawed Analysis

1. Upon a review of the detailed analysis of the various possible implementing regulations considered by the FDA, the Association confirms that the FDA did not adequately address all of the processing requirements contained within its proposed regulations when it proclaimed that this present option was the least onerous. For example, presently a shipment of produce containing two (2) different types of produce originating from five different growers but from a single shipper will require 2 OASIS line items and a single OASIS transmission. Under the proposed regulations, however, this same shipment would require 10 separate prior notice transmissions, in addition to the unchanged requirement for the OASIS filing. It is estimated that the cost to comply with the proposal, requesting such a dramatic increase in filing requirement would add 50%-60% to basic entry costs.

2. The FDA incorrectly assumes that the data required in the proposed regulations can be efficiently transmitted by submitters through the Internet using a basic computer and a $20.00 per month ISP service. In fact, based upon the experiences of U.S. Customs, even the ISDN high-speed technologies are not always sufficient to meet the data flow during peak times during the work day. Accordingly, the costs of high-speed data transmission and its associated programming, equipment and training expenses must also be factored into any substantive analysis of anticipated costs and burden. Moreover, the time necessary to develop these systems make the anticipated implementation date of December 12, 2003 impossible to meet.

3. The estimated labor cost for complying with the Proposed regulations did not contemplate the 24-hour personnel requirements that would be necessary to secure updated arrival information and other shipment data to submit appropriate prior notice amendments in due time. Moreover, the estimates did not consider that a single shipment may require the filing of literally thousands of prior notices, any one of which or all of which may require updating or amendments during the subsequent period prior to arrival.

4. The FDA assumes that only one employee and a supervisor will need to be trained in the new filing systems. This is unrealistic considering the number of increased submissions that will need to be filed, the verification operations that the brokers/importers will have to institute and the training of all parties included within the supply chain necessary in order to fulfill the registration requirements of all entities relevant to each subject food article.

F. Concerns Particular to Air Importations – Definition of "Port of Entry"

The Proposed Regulations do not distinguish between water, air or land transportation. This is not only an unfortunate consequence of insufficient trade input but, it is detrimental to air importations, in particular, because these shipments are subject to unique possibilities.

1. Of perhaps the greatest concern is the proposed definition of "Port of Entry" in the published regulations because air shipments may, for a variety of reasons, be split up. For example, the original 100 cartons destined to Los Angeles may ultimately become 30 cartons arriving first in Honolulu, 30 cartons arriving first in Anchorage, and 60 cartons arriving first directly in Los Angeles. These 100 cartons were originally all in tact and became divided only

as a result of overloaded cargo bins or unavailable direct flights. However, it would be impossible to amend the Prior Notice in sufficient time to accurately describe the varying Ports of Arrival...although the Port of Entry for each of the 100 cartons remains unchanged. Moreover, the importer or its broker may not even become aware of the splitting of the shipment until well after the permissible time for Prior Notice amendment or update or, in fact, perhaps not at all until actual arrival at the Port of Los Angeles.

2. The possibilities described in the foregoing paragraph would not only impact upon the impossible determination of Port of Arrival, but will also make it impossible to track differing times and dates of arrival from this original shipment of 100 cartons that may subsequently be split, for any of a great variety of legitimate reasons, into 2 or 20 or 50 separate air carriages. Accordingly, again, the Prior Notice updates and amendment procedures must remain flexible to allow for common, every day occurrences experienced in the normal course of business by air importers.

3. Even should the original air cargo remain intact, as is commonly known not only in this industry but in almost other parts of U.S. life, airlines have a tendency not to arrive on time. Should a normal delay occur that is not made known prior to arrival, there will be no method or manner to timely update the Prior Notice. Again, this is a normal occurrence experienced daily, if not more often, by persons within the industry working with air shipments and to require that a new Prior Notice be submitted because an airline was delayed due to a weather storm or other matter out of the control of the importer or its broker is unacceptable at best.

II. Suggestions for Amended FDA Regulations

A. Validation of Low-Risk Imports

Currently, many members of the Los Angeles importing community are participants in C-TPAT (Customs-Trade Partnership Against Terrorism) and also participate in the HACCP (Hazard Analysis and Critical Control Point) Program. Another importer that is a client of one of our brokers is currently using the BRASS (border release and selectivity system) to import their goods.

The C-TPAT and HACCP programs validate the security and safety protocols of the participants. The FDA must take the road of other governmental agencies equally concerned with the safety of the American marketplace by recognizing the efforts these businesses have already undergone to be validated as safe and low-risk importers. The FDA must not require businesses already certified as posing no threat to American health and safety and which have evidenced compliance with internal safety and security mechanisms to institute additional business procedures that would drive the costs of their remaining in business past the point of reasonableness. The FDA must reward these low-risk, cooperating importers with reduced entry and pre-arrival requirements instead of more.

In connection with the importer utilizing the BRASS system, it is confused as to how it is to provide entry information on the Prior Notice 24 hours prior to arrival when, under this program, Customs reads a bar code label upon entry and then assign an entry number prior to releasing the cargo. In other words, there is no entry information available to be indicated on the Prior Notice since it is not made available to importers in this program until the goods actually arrive. Accordingly, insofar as this BRASS system is an obvious attempt to streamline entry procedures and mitigate entry delays and unnecessary entry documentation, it is respectfully suggested that the Prior Notice content requirements be flexible so that importers qualifying and participating in programs intentionally instituted by U.S. Customs to benefit law-abiding and secure U.S. importers should not be penalized as a result of failure to adequately complete the Prior Notice document.

B. Reduce Possibility of Duplicative Work Efforts

If the FDA elects to receive all of the information it details in the proposed regulations as a part of the Prior Notice submission, then importers should not be required to provide the agency with the identical information post- arrival as well. This duplicative effort is uncalled for and serves no purpose. Currently, a lot of the entry-related information proposed to be included on the Prior Notice submission is already required of importers post-entry as a part of their submission through OASIS. Should the FDA opt to sample a shipment based on the information it receives about an item pre-arrival, then there is no reason for the importer/broker to provide it with that same information again after entry.

A far more efficient process would be to require the information presently asked for post-entry to be submitted in the form of Prior Notice during the proscribed time periods. In this way, the FDA would have at its fingertips, at one time, the information necessary to determine --- before arrival of any food article --- whether or not sampling should occur and whether or not an article should be released for admissibility purposes upon its arrival at a U.S. Port of Entry. This is similar to the system currently being used by Customs and the USDA that has a minimum impact on the flow of international trade but which provides a high level of confidence that the imported products are safe and secure. While the FDA will be meeting its obligations under the legislative mandate by requiring information currently provided post-entry prior to arrival, the importing community will not be subject to increased and duplicative work efforts and unnecessary increased costs of personnel and man hours.

C. Utilize Existing Information Systems

Much of the duplication of data and additional work burdens complained about by Association members could be eliminated if the FDA used data already being collected by other governmental agencies. For example, U.S. Customs is currently requiring the transmission of detailed manifest information 24 hours before any shipment is loaded onto an ocean carrier. It is anticipated that similar requirements will be published for all importations and exportation, without regard to mode of transport. As a result, prior to arrival, there will be available information on all products intended for entry at a U.S. port. Why will the FDA be unable to screen this information in order to determine which of those intended entries it must sample? Customs and the other government agencies must make this manifest information available to FDA so that this one pre-arrival submission can clearly meet the requirements set upon the FDA by Congress in the Bioterrorism Preparedness Act of 2002 and impacted importers/carriers and brokers are not, frankly, put out of business by contrary and duplicative federal agency requirements. Currently, the U.S. Department of Agriculture very successfully screens the manifest data in order to ensure the safety of products under its jurisdiction. There is no reason to believe that the FDA could not similarly utilize existing systems to accomplish its stated and legislatively mandated objectives.

In addition, the actual arrival time for all shipments could be easily and directly obtained by the FDA from Customs. If proper procedures and coordination existed between agencies, instead of distinct systems operating to the detriment of the importing community, then the FDA

would be able to have the updated arrival information automatically provided to it instead of needing to rely upon Prior Notice updates that, for all of the reasons set forth herein, will, more than likely, be unable to be timely submitted 24 hours a day every day of the year.

D. Provide Methods to Verify Information Submitted on Prior Notice Before Arrival

The regulations very clearly state that upon submission of the Prior Notice documentation, the importer or broker will only be provided with an acknowledgement of receipt. There will be no means to validate the data contained within the Prior Notice nor will the FDA make its own database public to permit submitters to verify the information prior to submission. Frankly, the only method for the FDA itself to verify the accuracy of all information contained within or upon the Prior Notice is to wait for submission of the entry documentation through OASIS or to ensure inspection of each and every food article arriving at a U.S. Port of Entry 24 hours a day, 365 days a year. Assuming the latter option is a fiction, for the benefit of both the FDA and the importing community, the proposed regulations must be amended to provide importers/brokers with the ability to verify the accuracy of the information submitted in a Prior Notice prior to arrival at the port. Only in this way, will the Agency itself be relieved of the responsibility to ensure adequacy of the Prior Notice before entry when such verification will, in most cases, only be possible after review of documentation through OASIS.

E. Rectify Ambiguities in Proposed Regulation

1. The registration requirements for a variety of food handlers are unclear at best. Clear exemptions and/or applications must be set forth for rail yards, container yards truck terminals, individual truckers, individual shipping storage facilities, air cargo handling agents, overnight carriers, couriers, container freight stations and similar cargo handlers which, in the case of a domestic transportation company, may require separate registration numbers for each individual facility or transporter within a literal army of such holding facilities. Not only would such an interpretation be overly burdensome but it will also be unnecessary to secure America's food supply. Moreover, the separate facility registration numbers of transporters or holding facilities through which a particular food article may only very briefly pass will be impossible to track by the Customs broker, importer or ultimate consignee. Accordingly, exemptions should

be specifically provided in the finalized regulations to rectify this ambiguity that may lead to additional burdens being placed upon legitimate food importers and Customs brokers.

2. The U.S. Agent's responsibilities and liabilities are unclear in the proposed regulations. Although Customs brokers are likely candidates to serve as U.S. Agents, they are not likely to volunteer for this role unless the regulations become much more specific and less ambiguous. On the one hand, U.S. Agents are said to only serve as a type of communication link between the FDA and the foreign food facility. However, U.S. Agents are also charged with the responsibility of binding the foreign food facility to statements submitted by the Agent on its behalf. Because the FDA is not required to consult with the foreign food facility directly on any matter as a result of its having an assigned U.S. Agent, the FDA has discharged itself of all such responsibility to communicate directly with the foreign food facility, leaving the possibility of sole liability resting only with the U.S. Agent. Certainly to the FDA itself, the U.S. Agent is merely an address to which the FDA may address communications. However, there is no question but that the U.S. Agent is a critical component of the relationship the FDA has with the applicable foreign food facility.

The regulations must clearly detail the responsibilities and the liabilities of the U.S. Agent. They must clearly indicate what will happen if the Agent transmits incorrect information, if it transmits information it had no authority to reveal or if it fails to communicate, whether intentionally or otherwise, information back to the foreign food facility relayed to it by the FDA. The appointed U.S. Agent must be provided with the means to relinquish its responsibilities officially by notification to the FDA and the foreign food facility must similarly have the right to remove an appointed U.S. Agent from those responsibilities. The regulations must contemplate liability in the event misinformation is provided to the Agency by the U.S. Agent in order that both the Agent and the foreign food facility are clearly advised of their respective roles and responsibilities.

It is unfair and unjust for the FDA to proffer regulations that only immunize the Agency from liability in the event there is a misunderstanding between the Agent and the foreign food facility. By creating an entity called a "U.S. Agent" the FDA must clearly define that entity's role and responsibility. While U.S. Brokers may elect to fulfill the role of a U.S. Agent in certain circumstances this will largely depend upon how the final regulations clarify related responsibilities and liabilities. In the event no such clarification is forthcoming, the FDA may

have a database of U.S. Agents unfamiliar with the importing process, uncommitted to both the foreign food facility and the American marketplace and who become unavailable and unresponsive in the event the FDA needs to reach a foreign food facility in an expeditious manner. Accordingly, the FDA is encouraged to more clearly describe the role of a U.S. Agent.

F. Provide Additional Time for Full Implementation

Many of the Association's members indicate that they are already overwhelmed by the incredible alterations to their current business operations required as a result of Customs 24-hour rule as well as the new AMS system. These members indicate that the newly proposed FDA regulations will only further confuse and complicate the entry and pre-arrival procedures beyond the point where any importer or U.S. consumer feels that the marketplace is any safer than it was the day before. Importations are already stalled and foreign exporters are already wary of the variety of new regulations, which seemingly place their products at risk of unreasonable port delays. It is reasonably feared that automatic implementation of the proposed FDA regulations without further consultation with impacted industry groups will only further obstruct international trade efforts and may, in fact, close any ongoing talks or negotiations intended to convince foreign exporters to re-enter the American marketplace.

In addition, with great respect, members of the LACBFFA are concerned by the obvious additional workload being undertaken by the FDA as a result of its proposed regulations. Although there is no question that the number of FDA port personnel has been recently increased, there is great apprehension about whether or not the Agency itself has the systems and means in place to inspect each and every of the over 20,000 Prior Notices it expects to receive each day to verify accuracy and timeliness (which, in our opinion, is an extremely low estimate). As already stated herein, the Association appreciates the underlying intention behind the proposed regulations but genuinely and respectfully suggests that the FDA re-examine the scope of the regulations they have proposed against the necessary content of those regulations as set forth by Congress in order to better determine whether the resulting increased workload on the FDA itself is justified or whether, in fact, that natural consequence will only lead to even more port delays and frustrations --- all of which work contrary to any objective of stopping terrorist activity at the border.

THE LOS ANGELES CUSTOMS BROKERS &
FREIGHT FORWARDERS ASSOCIATION, INC.

1949 - 2003 Serving Our Industry for 54 Years

Accordingly, it is urged that the FDA not implement any final regulations until a full spectrum of all current problems and proposals are discussed with the importing trade community. The FDA is urged to act in concert with other federal agencies and not independent of them as the international food industry becomes educated and adapts to the evolving U.S. importing rules and regulations. Unless the FDA intentionally seeks to confound any attempt to reinvigorate the American economy, the Agency must be willing to delay final implementation of its regulations until such time as the food industry has had sufficient opportunity to fully evaluate the impact and consult further with the FDA about any related concerns.

CONCLUSION

The proposed FDA food regulations would require brokers to increase their work spaces, personnel and hours of operations. The resulting increased costs would necessarily be passed on to importers who may, or may not, have the client demand to maintain the ongoing international food business. The proposed regulations threaten the entire global food business and the members of the Los Angeles Customs Brokers & Forwarders Association plead with the FDA to re-evaluate current information systems and other federal agency submission requirements in order to better determine whether the FDA's obligations under the Bioterrorism Preparedness Act of 2002 could perhaps be suitably met without jeopardizing this very important American business.

The U.S. economy is under enough hardship and jeopardy without the additional and unnecessary burden of FDA regulations requiring duplicative workloads and increased costs of doing business. The undersigned invites further discussion directly with the FDA and reiterates its sincere suggestion that the FDA specifically seek further trade-related input prior to finalizing any regulations governing food importation or distribution.

Respectfully submitted,

Maurine Cecil
President

Post Office Box 4250, Sunland, California 91041 • Telephone: (818) 951-2841 • FAX: (818) 353-5976 • E-Mail· la.cbffa@verizon.net
Website: www.lacbffa.org